

REMARKS

Upon entry of the following amendments, claims 1-4, 6-9, and 11-19 constitute the pending claims in the present application. Claims 3, 5, and 10 are cancelled. Claims 1-4, 6-9, and 11-18 are rejected. Claim 19 is newly added.

Applicants note that the Office considers claims 3, 5, and 10 to be withdrawn from consideration (see page one of the outstanding action under "Office Action Summary"). However, Applicants note that these claims were previously cancelled and are appropriately identified as such.

Support for claim 19 can be found throughout the application as filed. For example, in Figs. 1, 2, and 2A-C. Applicants assert claim 19 adds no new matter.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1-14. Double Patenting Rejections and Claims Rejections under 35 U.S.C. 103(a)

Claims 1, 2, 4, 6, 7-9, 11-18 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 10-20 of co-pending Application No. 10/973,191 (the '191 application). Without addressing the merits of this rejection, Applicants note that since this is a "provisional" rejection, upon a finding of the present claims as otherwise allowable, this "provisional" rejection will be withdrawn pursuant to the pendency of the '191 application (MPEP 804).

Applicants further note that the Office has also rejected the claims of the '191 application over the present application under 35 U.S.C. 103(a) (see page 2, second to last paragraph of the outstanding action: "Claims [sic] 1 of US Application No.: 10/973,191 are [sic] rejected under 35 U.S.C. 103(a) as being unpatentable over US Application No.: 9/874,302"). 35 U.S.C. 131 provides: "The Director shall cause an examination to be made of the application..." (emphasis added). As such, Applicants respectfully point out that the claims of only one application should be examined and that rejections of claims of a second application, in this case those of the '191

application, are properly advanced only in the course of prosecution of the second application. Accordingly, Applicants request reconsideration and withdrawal of this obviousness rejection.

15. Claim Objections

Claim 13 is objected to because of a typographical error. Applicants have amended claim 13 to correct the location "in" in this claim thereby rectifying the typographical error.

16-17. Claim Rejections – 35 U.S.C. 112

Claims 13 and 14 are rejected under 35 U.S.C. 112 second paragraph as allegedly being indefinite. The Office contends that the word "maybe" renders the claim indefinite because it is unclear whether the limitation(s) following the word would actually occur in the use of the instrument. Applicants have amended claims 4 and 13 to delete the word "maybe" replacing it with the words "may be" thereby correcting an unintentional typographical error. Applicants request reconsideration and withdrawal of the rejection of claim 13.

Although the Office has rejected claim 14 for similar reasons as noted above for claim 13, Applicants note that claim 14 does not recite the word "maybe," nor is claim 14 even dependent on claim 13. Applicants presume that it was the Office's intention to indicate that claim 4 had been rejected for indefiniteness for recitation of "maybe." However, if this is not the case, Applicants respectfully request clarification.

18-32. Claim Rejections – 35 U.S.C. 103

Claims 1, 2, 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. published patent application 2004-0176802 to Skiba et al. ("Skiba") in view of U.S. 5,860,993 to Thompson et al. ("Thompson").

The Office contends that Skiba discloses a surgical instrument comprising a handle (1802) with a curved portion (figure 25), a tip (1808), and a window (figure 20) including an L-shaped slot (figure 20). The Office acknowledges that Skiba fails to disclose a blunt tip. The Office asserts that Thompson teaches "that a tip can be smooth and rounded." The Office then states in conclusory fashion, "Therefore, it would have been obvious ... to use Thompson's blunt tip on Skiba's surgical

instrument in order to conduct blunt dissection of tissue." Applicants traverse the rejection since a *prima facie* case of obviousness has not been established.

Pursuant to MPEP 2142:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In presenting the outstanding obviousness rejection over Skiba in view of Thompson, the Office has not provided any rationale for why the one of ordinary skill would be motivated to combine the teachings of these two references. Instead the Office only offers the unsupported conclusion that "it would have been obvious." In order to satisfy its burden of establishing a *prima facie* case of obviousness, the Office must establish why the *references* would motivate one of ordinary skill to modify the teachings therein to arrive at the claimed invention. Simultaneously, the Office should be mindful that "the level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999)." MPEP 2143.01. Since the Office has not shown or attempted to show the required motivation, the *prima facie* case of obviousness has not been demonstrated.

Moreover, Applicants assert that one of skilled in the art would *not* have been motivated to combine the teachings of Skiba and Thompson. In every embodiment taught, Skiba instructs that the tip of the disclosed device is sharpened for piercing tissue (see paragraph 0047, for example). Skiba further teaches that the sharpened tips of the devices can be replaced in the event the tips become dull (see paragraph 0050). Hence Skiba clearly teaches that dull, *i.e.*, blunt tips, are disadvantageous and provides methods for changing the tips if they do become dull/blunt. Skiba clearly *teaches away* from the presently claimed surgical instrument with a blunt tip and provides no motivation to modify the device therein to accommodate a blunt tip.

Furthermore, Thompson teaches that the tip 27 of the device therein is "preferably smooth and rounded in order to *prevent* injury" (emphasis added) (see column 4, lines 59-61). This directly conflicts with the intention of the Skiba device which is to penetrate tissue, *i.e.*, to injure tissue. Hence, Thompson specifically teaches that modification of the Skiba device to include the tip of Thompson would run counter to the intended purpose of the Skiba device. According to MPEP 2143.01, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." Thus, there is no motivation to modify the Skiba device with the teachings of Thompson since the teachings of the cited art explicitly discourage it.

Applicants respectfully remind the Examiner that under MPEP 2143 the Examiner cannot rely on the present application as a blueprint for providing the motivation to combine the teachings of Skiba and Thompson references. Additionally, as instructed by MPEP 2141, "The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention."

In order to establish a *prima facie* case of obviousness, the Office must also demonstrate that there is a reasonable expectation of success in combining the teachings of the cited references. Again, the Office has provided no evidence or reasoning to satisfy this requirement.

Applicants assert that one of ordinary skill at the time of filing the present application would *not* have had a reasonable expectation of success in combining the teachings of Skiba and Thompson as suggested by the Examiner. In particular, Skiba suggests that configuring a Skiba device with a dull/blunt tip would perform unsatisfactorily and certainly worse than a Skiba device with a sharpened tip. The teachings of Thompson further confirm that a Skiba device with a dull/blunt would discourage tissue penetration when compared with a Skiba device with a sharpened tip. As such, both of the cited references lead one of skill in the art to the conclusion that combination of the two teachings as suggested by the Examiner would lead to an inferior and potentially inoperable device, *i.e.*, would not lead to a reasonable expectation of success.

For the reasons above, Applicants assert that at least two of the required elements of establishing a *prima facie* case of obviousness, motivation and expectation of success, have not been met. Accordingly, instant claim 1 and those dependent there on are not obvious over Skiba in view of Thompson. Applicants request reconsideration and withdrawal of the rejection.

33-34. Claim Rejections – 35 U.S.C. 103

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skiba in view of Thompson and U.S. 6,254,620 to Koh et al. ("Koh"). The Office submits that Koh teaches an increased frictional arrangement on the surface of a handle (12). However, Applicants note that Koh does not provide a motivation for or expectation of success in combining the teachings of Skiba and Thompson. As such, Koh does not remedy the deficiencies of the rejection of claim 1 from which claim 6 depends. Consequently, claim 6 is not obvious over Skiba in view of Thomson and Koh, and Applicants request reconsideration and withdrawal of the rejection.

Applicants Request List of References Cited by Applicants and Considered by Examiner

As a final point, Applicants note that there is no indication of record that U.S. 5,860,993 to Thompson et al. has been considered by the Examiner since an initialed copy of the information disclosure statement (IDS) mailed by Applicants on January 14, 2005 citing U.S. 5,860,993 to Thompson et al. has not been forthcoming from the Office. Applicants respectfully request that pursuant to MPEP 609.05(b) an initialed copy of the January 14, 2005 IDS be mailed to Applicants. Applicants also request that any references relied on by the Office be included on a form PTO-892 so that these references are printed on the front page of any patent that may issue from the pending application.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. MIY-P01-011 from which the undersigned is authorized to draw.

Dated: December 8, 2006

Respectfully submitted,

By 

Carl A. Morales

Registration No.: 57,415

FISH & NEAVE IP GROUP,

ROPES & GRAY LLP

One International Place

Boston, Massachusetts 02110-2624

(617) 951-7000

(617) 951-7050 (Fax)

Attorneys/Agents For Applicant